

January 2, 2001

DRS OPTRONICS, INC. 2330 Commerce Park Drive, N.E. Palm Bay, FL 32905

http://www.drs.com 321.984.9030 FAX 321.984.8746

Dockets Management Branch (HFA-305) Food & Drug Administration, Room 1-23 12420 Parklawn Drive Rockville, MD 20857

2281

Subject:

Application for Exemption

To Laser Products Performance Standards

CFR Title 21, 1040.10 and 1040.11

A9:16

Gentleman:

DRS Optronics, Inc. manufactures the NIGHSTAR BINOCULAR SYSTEM, which contains an Eye Safe Laser Rangefinder. However, it also contains a class III b Laser Pointer which is not compliant with the FDA provisions of CFR Title 21, Part 1040.

The NIGHTSTAR BINOCULAR SYSTEM is intended for use by the US military and other US agencies for night observation and surveillance. Compliance with some of the laser performance standards are inconsistent with the military mission and inappropriate for covert missions where this product will be primarily used.

Enclosed for your review is the NIGHTSTAR BINOCULAR SYSTEM Specification Sheet, which provides a description of this product.

DRS Optronics, Inc. has received an order for this product, from the General Services Administration (GSA), for 24 units to be provided to the US Border Patrol. A copy of that order is also enclosed.

The areas of noncompliance with the performance standards of 1040.10 are as follows:

- No safety interlock that prevents human access to laser radiation when the housing is removed.
- No visual or aural indication of interlock defeat
- No remote interlock connector that prevents human access when removed.
- No key actuated master control
- No audible or visible indicator in advance of emissions that allow action to avoid exposure
- No built in beam attenuator
- No internal warning labels



Compliance with the safety interlocks, indication of interlock defeat and internal warning labels will not restrict the use of the system, but it deemed inappropriate since the unit is not user maintainable (i.e. the cover cannot be removed due to the use tamper resistant hardware). Unless the user deliberately defeats the tamper resistant hardware, the cover will never be removed except by the manufacturer.

The use of a remote interlock connector is inappropriate of this product. The word "remote" implies a situation where the laser and the control for the laser are separate from each other (i.e. remotely located). This remote interlock connector allows someone at the laser aperture to disable the "remote" controls while the controls are out of sight or not under direct control of the operator. Since this is a hand held item, there are no "remote" locations in the system. Consequently a "remote interlock" is not appropriate. The operator always has full control of the laser.

For the beam attenuator, a dense rubber lens cover is used, thereby providing the beam attenuator function.

Compliance with the key actuated master control is inconsistent with the military mission since keys are easily lost in a combat environment, possibly resulting in loss of life or mission failure. Likewise, an audible or visible indication in advance of emissions is inconsistent with the covert missions where this product is primarily used. At great expense we have reduced or eliminated visual or audible emissions for reasons of survivability. There is a display change, when the laser pointer is armed, that does provide an advance warning of emissions to the operator if he is looking through the display.

The advantage of this deviation is increased survivability, through limited detection possibilities, and improved mission success (keys get lost and flashing lights or beeps reveal your position).

Proper training of personnel and restriction of use of the product to only trained personnel provides radiation protection. Also, the use of tamper resistant hardware prevents inadvertent user access to radiation.

The period of time that DRS Optronics, Inc. desires the exemption to be in effect is 7 years (through 12/31/07). Although this first order is only for 24 units, DRS Optronics, Inc. expects to sell several hundred more units for use by the US Border Patrol, as well as several hundred to other US Government agencies, and various law enforcement agencies.

Should any additional information be required, please do not hesitate to contact the undersigned at (321) 984-9030.

Sincerely.

George Hickman

Director, Contract Administration

cc: Sonya Bottari, Bob Moore, Craig Smith

File: 8227

DRS's NIGHTSTAR™ BINOCULAR SYSTEM

DRS Optronics' hand-held night viewing binocular incorporates an image intensifier tube, laser rangefinder, digital compass and inclination/elevation measurement in a compact lightweight system ideal for infantry units, special forces and night operations involving forward observers and reconnaissance patrols.

With a range of 20 to 2,000 meters, this fully eye-safe (Class 1) and simple-to-operate device displays range, azimuth and elevation data in the soldier's eyepiece. This allows the soldier to identify targets and relay essential fire support information for engagements during the darkness of night. This system offers interface ability of transmitting the range, azimuth and elevation data to external systems, such as GPS and other combat computers, for immediate coordinate definition. In addition an optional long-range IR pointer can be built into the system.

DRS OPTRONICS, INC.



NIGHTSTAR™ BINOCULAR SYSTEM technical specifications

viewing

Some Highlights Include:

Lightweight and compact

Range of 20 to 2,000 meters

Displays the range, azimuth and elevation data in eyepiece

P/N: DRSO-82858 NSN: 5855-01-463-4044

9
Magnification 3x Diopter Setting +2 to -6 IPD 54 to 72 mm Exit Pupil 7 mm Eye Relief 15 mm Objectivity F# 1.3 Image Tube Resolution 64 lp/mm Type 3rd Generation
laser
Type GaAs Laser Diode Wavelength 904 nm Output 2.85 watt Safety Full Eye-Safe (Class 1), (ANSI Z 136.1)
ranging
Sensor Type APD Range 20 to 2,000 meters Range Accuracy +/- 5m at 2,000 m Receiver 3.3 mrad Measuring Time 1.0 seconds
compass
Sensor Type Flux Gate Accuracy 1.5 degrees RMS Tilt Up to +/- 20 degrees
inclinometer
Type
display
Numeric
general
Power Source

1,000 ranging and 1,000 azimuth measurements

DRS OPTRONICS, INC.



environment Complies with MIL-STD 810D

2330 Commerce Park Drive, NE Palm Bay, FL 32905

321.984.9030 Fax 321.984.8796 email: optronics@drs.com http://www.drs.com

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viewing
Magnification 3x Diopter Setting +2 to -6 IPD 54 to 72 mm Exit Pupil 7 mm Eye Relief 15 mm Objectivity F# 1.3 Image Tube Resolution 64 lp/mm Type 3rd Generation
laser
Type GaAs Laser Diode Wavelength 904 nm Output 2.85 watt Safety Full Eye-Safe (Class 1), (ANSI Z 136.1)
ranging
Sensor Type APD Range 20 to 2,000 meters Range Accuracy +/- 5m at 2,000 m Receiver 3.3 mrad Measuring Time 1.0 seconds
compass
Sensor Type
inclinometer
Type
display
Numeric 4-Digit 7-Segment Type for Azimuth and Range, 2-Digit 7-Segment for Memory Reticle
general
Power Source
C

DRS OPTRONICS, INC



environment Complies with MIL-STD 810D

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Form 1449







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COLIGITATION						
SOLICITATION/COM	ITEMS		1. REQUISITION NU A04911483	MBER	PAGES 1 OF (1) PAGE(S)	
OFFEROR TO COM	PLETE BLOCKS	<i>12, 17, 23, 24, & 30.</i>				
2. CONTRACT NO. GS05T01BMM0003	1. AWARD/EFFECTIVE DATE 11/28/2000	4. ORDER NUMBER	5. SOLICITATION NU T0501BQ0001	IMBER	6. SOLICITATION ISSUE DATE	
7. FOR SOLICITATION INFORMATION CALL:	a. NAME Ellen Womack	,	b. TELEPHONE NUMBER (No Coilect Calls) (312) 353-2667		8. OFFER DUE DATE/ LOCAL TIME	
9. ISSUED BY GSA Region 5 - Chicago Howard Norns 230 S. Dearborn Street Chicago, IL 60604 United States (312) 886-8814		10. THIS ACQUISITION IS X UNRESTRICTED SET ASIDE: % FOR SMALL BUSINESS SMALL DISAV. BUSINESS 8(A)		11. DELIVERY FOR FOB DESTINATION Destination	12. DISCOUNT TERMS Net 30 Days	
-		SIC: SIZE STANDARD: 500 employees		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		
				13b. RATING N/A 14. METHOD OF SOLICITATION		
15. DELIVER TO Lawrence Henson 801 I Street NW, Room 740 INS OIRM Washington, DC 20536 United States		16. ADMINISTERED BY Ellen L. Womack (312) 353-2667				
Stan R Sheridan DRS OPTRONICS INC. 2330 Commerce Park Dr. Palm Bay, FL 32905		18a. PAYMENT WILL BE MA William Totten 801 I Street NW, Room 740 INS OIRM Washington, DC 20536 United States	ADE BY			
17b. CHECK IF REMITTANCE DIFFERENT AND PUT SUCH A		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED				
19. ITEM NO.	20. SCHEDÜLÉ ÖF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT	
	NIGHTSTAR BINOCULARS P/N: DRSO-82858 NSN: 5855-01-463-4044 Includes: GEN III mage intensifier tube gated, magnification power 3X, range finder, nfrared pointer, ntegrated inclinometer, azimuth range display, automatic built in test, RS-232 interface port,	24	EA	12,867.55	308,821.20	

carrying ca strap, oper manuals, 2 warranty ai training.	ator year nd trainer								
25. ACCOUNTING AND APPROPRIATION	\$308,821.20								
27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-5 ARE ATTACHED. ADDENDA ATTACHED. 27b. 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ARE NOT ATTACHED.									
28. CONTRACTOR REQUIRED TO SIGN COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH A OR OTHERWISE IDENTIFIED ABOVE AN SUBJECT TO THE TERMS AND CONDIT	ND DELIVEI	R ALL ITEMS SET FORTH ADDITIONAL SHEETS	29. AWARD OF CONTRACT: REFERENCE BID B8227OFFER DATE 11/20/2000. YOUR OFFER ON SOLICITATION (BLOCK 5) INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:						
30a. SIGNATURE OF OFFEROR/CONTR.	ACTOR	31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) Ellen L. Womack							
30b. NAME AND TITLE OF SIGNER (Type or print)	30c. DATE	SIGNED	31b. NAME OF CONTRACTING OFFICER (Type or print) Ellen L. Womack (312) 353-2667		31c. DATE SIGNED 11/28/00				
32a. QUANTITY IN COLUMN 21 HAS BEE	N								
32b. SIGNATURE OF AUTHORIZED GOVT. REPRESENTATIVE	32c. DATE	·		39. S/R VOUCHER NUMBER	40. PAID BY				
	42a. RECEIVED BY (Print)	(Print)							
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	42b. RECEIVED AT (Location)								
CERTIFYING OFFICER		42c. DATE REC'D (YY/MM/DD)		42d. TOTAL CONTAINERS					
AUTHORIZED FOR LOCAL REPRODUCTION		SEE REVERSE SIDE FOR OMB CONTROL NUMBER ANDPAPERWORK BURDEN STATEMENT		STANDARD FORM 1449 (10-95) Prescribed by GSA - FAR (48 CFR) 53.212					

Edit History

PURCHASE ORDER TERMS AND CONDITIONS

552.229-70 FEDERAL, STATE, AND LOCAL TAXES (APR 1984) The contract price includes all applicable Federal, State, and local taxes. No adjustment will be made to cover taxes which may subsequently be imposed on this transaction or changes in the rates of currently applicable taxes. However, the Government will, upon the request of the Contractor, furnish evidence appropriate to establish exemption from any tax from which the Government is exempt and which was not included in the contract price.

PACKING LIST

(a) A packing list or other suitable shipping document shall accompany each snipment and shall indicate (1) Name and address of consignor; (2) Name and address of consignee; (3) Government order or requisition number; (4) Government bill of lading number covering the shipment (if any); and (5) Description of the material shipped, including item number, quantity, number of containers, and package number (if any).

(b) When payment will be made by Government commercial credit card, in addition to the information in (a) above, the packing list or shipping document shall include; (1) Cardholder name and telephone number and (2) the term "Credit Card."

52.232-1 PAYMENTS (APR 1984)

The Government shall pay the Contractor, upon the submission of proper invoices or vouchers, the prices stipulated in this contract for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this contract. Unless otherwise specified in this contract, payment shall be made on partial deliveries accepted by the Government if -- (a) The amount due on the deliveries warrants it; or (b) The Contractor requests it and the amount due on the deliveries is at least \$1,000 or 50 percent of the total contract price.

52.232-8 DISCOUNTS FOR PROMPT PAYMENT (MAY 1997)

(a) Discounts for prompt payment will not be considered in the evaluation of offers. However, any offered discount will form a part of the award, and will be taken if payment is made within the discount period indicated in the offer by the offeror. As an alternative to offering a prompt payment discount in conjunction with the offer, offerors awarded contracts may include prompt payment discounts on individual invoices.

(b) In connection with any discount offered for prompt payment, time shall be computed from the date of the invoice. If the Contractor has not placed a date on the invoice, the due date shall be calculated from the date the designated billing office receives a proper invoice, provided the agency annotates such invoice with the date of receipt at the time of receipt. For the purpose of computing the discount earned, payment shall be considered to have been made on the date that appears on the payment check or, for an electronic funds transfer, the specified payment date. When the discount date falls on a Saturday, Sunday, or legal holiday when Federal Government offices are closed and Government business is not expected to be conducted, payment may be made on the following business day.

PROMPT PAYMENT

Prompt Payment clause 52.232-25 is incorporated in this contract by reference. The clause contains information on payment due date, invoice requirements, constructive acceptance and interest penalties. Certain portions of the clause regarding payment due date, invoice requirements, and constructive acceptance have been Extracted for your convenience. All days referred to in the extracts below are calendar days.

(a) (1) The due date for making invoice payments by the designated payment office shall be the later of the following two events:

NOTE: Invoices must include the ACT number (block 4) and shall be submitted in an original only, unless otherwise specified to the billing office designated in block 24 to receive invoices. The *remit to* address must correspond to the remittance address in block 12.

(a) (5) (i) For the sole purpose of computing an interest penalty that might be due the Contractor, Government acceptance shall be deemed to have occurred constructively on the 7th day (unless otherwise specified in block 20) after the Contractor delivered the supplies or performed the services in accordance with the terms and conditions of the contract, unless there is a disagreement over quantity, quality, or Contractor compliance with a contract provision.

YEAR 2000 COMPLIANCE FOR INFORMATION TECHNOLOGY (IT) IT being acquired under this contract shall accurately process date/time data (including but not limited to calculating, comparing and sequencing) from, into and between the 20th and 21st centuries, and the years 1999 and 2000 and leap year calculations to the extent that other IT, used in combination with the IT being acquired, properly

exchanges date/time data with it

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address (es): http://web.deskbook.osd.mil

FEDERAL ACQUISITION REGULATION (48 CFR CH1) CLAUSES

Applicable to purchase orders for supplies or services:

52.222-41 SERVICE CONTRACT ACT AS AMENDED (MAY 1989)
The GSA Form 2166, Service Contract Act of 1965 and Statement of
Equivalent Rates for Federal Hires is attached hereto and made a part
hereof

52.222-42 STATEMENT OF EQUIVALENT RATES FOR FEDERAL HIRES (MAY 1989)

(52.222-41 and 52.222-42 apply to service contracts when the amount exceeds \$2.500.00).

52.203-3 GRATUITIES (APR 84)

52.212-9 VARIATION IN QUANTITY (APR 84) (The permissible variations are stated in the schedule)

52.222-3 CONVICT LABOR (AUG 96)

52.222-26 EQUAL OPPORTUNITY (FEB 99) (Applies when amount exceeds \$10,000.)

52.222-35 — AFFIRMATIVE ACTION FOR DISABLE VETERANS AND VETERANS OF THE VIETNAM ERA (APR 1998) (Applies when amount exceeds \$10,000.)

52.222-36 — AFFIRMATIVE ACTION FOR WORKERSWITH DISABILITIES (JUN 1998) (Applies when amount exceeds \$2,500.) 52.222-37 EMPLOYMENT REPORTS ON DISABLED VETERANS AND VETERANS OF THE VIETNAM ERA (JAN 1999) (Applies whenever Clause 52.222-35 is included.)

52.223-6 DRUG FREE WORKPLACE (JAN 97) (Applies if contract is awarded to an individual.)

52.225-3 BUY AMERICAN ACT - SUPPLIES (FEB 00)

52.225-11 RESTRICTIONS ON CERTAIN FOREIGN PURCHASES (FEB 00)

52.232-25 PROMPT PAYMENT (JUN 97)

52.233-1 DISPUTES (DEC 98)

52.233-3 PROTEST AFTER AWARD (AUG 96)

52.246-1 CONTRACTOR INSPECTION REQUIREMENTS (APR 84) 52.249-8 DEFAULT (FIXED PRICE SUPPLY AND SERVICE) (APR 84)

- (i) The 30th day after the designated billing office has received a proper invoice from the Contractor...
- (ii) The 30th day after Government acceptance of supplies delivered or services performed by the Contractor...
- (a) (3) The Contractor shall prepare and submit invoices to the designated billing office specified in the contract. A proper invoice must include the items listed in (a)(3)(i) through (a)(3)(iii)... If the invoice does not comply with these requirements, it shall be returned within 7 days after the date the designated billing office received the invoice... Untimely notification will be taken into account in computing any interest penalty owed the Contractor.
- (i) Name and address of the Contractor.
- (ii) Invoice date. (The Contractor is encouraged to date invoices as close as possible to the date of the mailing or transmission.)
- (iii) Contract number or other authorization for supplies delivered or services performed (including order number and contract line item number).
- (iv) Description, quantity, unit of measure, unit price, and extended price of supplies delivered or services performed.
- (v) Shipping and payment terms (e.g., shipment number and date of shipment, prompt payment discount terms). Bill of lading number and weight of shipment will be shown for shipments on Government bills of lading.
- (vi) Name and address of Contractor official to whom payment is to be sent (must be the same as that in the contract or in a proper notice of assignment).
- (vii) Name (where practicable), title, phone number, and mailing address of person to be notified in event of a defective invoice.
 (viii) Any other information or documentation required by the contract (such as evidence of shipment.)

Applicable to purchase orders for supplies:

52.222-20 WALSH-HEALEY PUBLIC CONTRACT ACT (DEC 96) (Applies when amount exceeds \$10,000.)
52.243-1 CHANGES -FIXED PRICE (AUG 87)
52.249-1 TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (FIXED PRICE) (SHORT FORM) (APR 84)

Applicable to purchase orders for services:
52.222-4 CONTRACT WORK HOURS AND SAFETY STANDARDS
ACT - OVERTIME COMPENSATION (JUL 95) (Applies when amount
exceeds \$2500.)
52.243-1 CHANGES - FIXED PRICE (AUG 87) - Alt. II
52.249-4 TERMINATION FOR CONVENIENCE OF THE
GOVERNMENT (SERVICES) (SHORT FORM) (APR 84)

GSA FORM 300 BACK (REV 4-00)

Customer: This service area is provided for your internal use and convenience. Service must be marked on airbill.

Standard FedEx Service:

Michele Wells (321)984-9030 FROM:

DRS Optronics, Inc.

2330 Commerce Park Drive NE

Suite 2 Palm Bay, FL 32905

Dockets Management Branch (HFA- (301)827-3990

Food & Drug Administration 12420 Parklawn Drive

Room 1-23

Rockville, MD 20857-

REF:

TO:



STANDARD OVERNIGHT CAD # 3087179

WED

TRK # 7919 3453 7350 FORM 0201

Deliver By: 03JAN01

SHIPPER'S FEDEX ACCOUNT NUMBER

20857-MD-US



Insert airbill here



Federal Express

SHIP DATE: 02JAN01 MAN-WGT: 1 LBS